K021576

ENCLOSURE L

NOV 4 2002

Premarket Notification (510(k) - Mercury Medical STATCO$_2$™ End Tidal CO$_2$ Detector

Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness

May 10, 2002

Mercury Enterprises, Inc./Mercury Medical
11300 49th St. N.
Clearwater, Fl. 33762
Tel: (800) 237-6418
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Official Contact: **Ron Rupenski**
Director, QA/RA

Proprietary or Trade Name: Mercury Medical STATCO$_2$™ End Tidal CO$_2$ Detector

Common/Usual Name: Mercury Medical CO$_2$ Detector

Classification: Class II, 73CCK, 21 CFR 868.1400

Classification Name: ET Tube Placement Detector

Device: STATCO$_2$™ End Tidal CO$_2$ Detector

Predicate Devices: Nellcor, Easy Cap II, K894053 (FENEM submitter)

Device Description:

The Mercury Medical STATCO$_2$™ uses the same technology as the Nellcor Easy Cap II, (K894053, FENEM submitter). The STATCO$_2$™ End Tidal CO$_2$ Detector is a "Single Patient Use" only device. The device assists in verification of tube placement during endotracheal or nasotracheal intubation. It may be used on intubated patients to detect approximate ranges of end tidal CO$_2$ when clinically significant.

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The device consists of a housing unit made with material of polycarbonate, filter media consisting of 3M Filtrete GSB30 and Bregas C-it Indicator, 510(k) K000520 mounted to the housing.

Intended Use:

Indicated Use: The Mercury Medical STATCO$_2$^{TM} End Tidal CO$_2$ Detector is to provide a semi-quantitative visualization of the CO$_2$ in the patient airway. It is an adjunct in patient assessment, to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a physician.

Technical Characteristics: The device has the same technical characteristics as the predicate device marketed by Nellcor, Easy Cap II.

Non-Clinical Data: Performance and specifications of the modified device are consistent with all requirements for this device type specified by ISO 5356-1: 1987 – Anesthetic and Respiratory Equipment-Conical connectors-Part 1: Cones and Sockets. ASTM F1054 – Standard Specification for Conical Fittings of 15mm and 22mm sizes.

Environment of Use: Hospital/Transport

Conclusions: The comparison to the predicate devices demonstrates that the proposed device is safe and effective and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 4 2002

Mr. Ron Rupenski
Director, QA/RA
Mercury Medical
11300 49th Street North
Clearwater, Florida 33762-4800

Re: K021576
Trade/Device Name: Mercury Medical STATCO$_2$™ End Tidal CO$_2$
Regulation Number: 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: September 3, 2002
Received: September 5, 2002

Dear Mr. Rupenski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: _K021576_____

Device Name:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _X_ **or** **Over-the-counter use __**
(Per CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K021576